

**WHO-PQ RECOMMENDED  
PATIENT INFORMATION LEAFLET**

## **PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER**

### **Rifampicin 300 mg Capsules\* rifampicin**

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet; you may need to read it again.
- If you have any further questions, ask your health care provider.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, tell the health care provider. This includes any side effects not listed in this leaflet. See section 4

#### **What is in this leaflet**

1. What Rifampicin 300 mg Capsules is and what it is used for
2. What you need to know before you take Rifampicin 300 mg Capsules
3. How to take Rifampicin 300 mg Capsules
4. Possible side effects
5. How to store Rifampicin 300 mg Capsules
6. Contents of the pack and other information

#### **1. WHAT RIFAMPICIN 300MG CAPSULES IS AND WHAT IT IS USED FOR**

Rifampicin 300 mg Capsules contains the active ingredient rifampicin. Rifampicin belongs to a group of medicines called rifamycin antibiotics. Rifampicin 300 mg Capsules used in combination with other anti-tuberculosis medicines is for the treatment of tuberculosis (TB).

#### **2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE RIFAMPICIN 300 MG CAPSULES**

##### **You should not take Rifampicin 300 mg Capsules:**

- if you are hypersensitive (allergic) to rifampicin, or any of the other ingredients of Rifampicin 300 mg Capsules (see section 6, What Rifampicin 300 mg Capsules contains).
- if you have acute liver disease,
- if you have drug-induced liver disease,
- if you have experienced liver damage linked to rifampicin before,
- if you are using voriconazole (a medicine used to treat fungal infections)
- if you are taking boceprevir, daclatasvir, ledipasvir or sofosbuvir (medicines used to treat the Hepatitis C infection) or a medicine against HIV infection that belongs to the class of protease inhibitors.

##### **Warnings and precautions**

Rifampicin 300 mg Capsules may cause liver disease (hepatitis). You should be attentive to symptoms that might be due to liver damage, such as unexplained loss of appetite, nausea, vomiting, dark urine,

\*Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility. Throughout this WHOPAR the trade/proprietary name is given as an example only.

yellow discolouration of the skin (jaundice), persistent fatigue of greater than 3 days duration and abdominal pain and tenderness. If these occur, you should immediately report this to your healthcare provider.

You may be at special risk for developing hepatitis:

- if you are older than 35 years,
- if you drink alcoholic beverages daily (see “Taking Rifampicin 300 mg Capsules with food and drink”)
- if you have a chronic liver disorder
- if you are a user of injection drugs (e. g. heroin)

If you belong to one of these groups your healthcare provider will closely check your liver function.

Furthermore, you will be carefully monitored:

- if you use any chronically administered medication concurrently (see “Taking other medicines”),
- if you are pregnant
- if you are HIV infected.

If you get flu-like symptoms such as fever, headache, muscle aches etc., you should report this to your health care provider, since Rifampicin 300 mg Capsules may be the cause.

If you have epilepsy or a history of psychiatric disease, you should report this to your health care provider, since it may affect your ability to tolerate Rifampicin 300 mg Capsules.

If you have kidney problems, diabetes or porphyria, it is important that you inform your health care provider about this, since Rifampicin 300 mg Capsules may then be unsuitable for you.

If you are taking cortisone or any cortisone-like drug, you should report this to your health care provider, since the cortisone dose may have to be increased while taking Rifampicin 300 mg Capsules.

Rifampicin 300 mg Capsules may cause a reddish-orange discolouration of body fluids such as urine, sputum and tears. This is due to rifampicin, and does not require medical attention. Also, contact lenses may become discoloured due to Rifampicin 300 mg Capsules.

Rifampicin 300 mg Capsules may lower the effects of oral contraceptive pills. Therefore, a different or additional method of contraception (e.g. condoms, intra-uterine device, pessary) should be used during treatment with Rifampicin 300 mg Capsules.

It is important that your health care provider knows about all your symptoms, even when you think they are not related to tuberculosis infection.

Your health care provider will need to check your blood before you take this medicine. This will help your health care provider know if any changes happen to your blood after taking this medicine. You may also need to have regular blood tests to check how your liver is working.

If you need a blood test to check bilirubin, folate or vitamin B12 levels tell your health care provider you are taking Rifampicin 300mg Capsules as it may affect your results.

### **Taking other medicines**

Tell your health care provider if you are taking, have recently taken any other medicines, including medicines obtained without a prescription, or the following:

- anticoagulants to thin the blood eg. warfarin
- anti-inflammatory medicine called corticosteroids eg. prednisolone
- medicine used after an organ transplant eg. ciclosporin, sirolimus, tacrolimus
- medicine to treat a heart condition eg. digoxin, digitoxin, quinidine, disopyramide, mexiletine, propafenone, tocainide, calcium channel blockers (diltiazem, nifedipine, verapamil, nimodipine, isradipine, nocardipine, nisoldipine)
- medicine to lower blood pressure eg. bisoprolol, propranolol, losartan, enalapril
- diuretics (water tablets) such as eplerenone
- antidiabetic medicine eg. chlorpropamide, tolbutamide, gliclazide, rosiglitazone
- antiepileptics eg. phenytoin
- strong painkillers eg. morphine, methadone
- sedatives (sleeping tablets) or medicine for anxiety eg. amobarbital, diazepam, zopiclone, zolpidem
- hormone-blocking medicine such as tamoxifen, toremifene, gestrinone
- medicine containing hormones such as oestrogen, progestogens eg. hormonal contraceptives. If you are taking an oral contraceptive to prevent pregnancy while you are taking Rifampicin 300mg Capsules, the contraceptive may not work (see “Pregnancy and breast-feeding”)
- thyroid medicine eg. levothyroxine
- medicine for mental illness eg. haloperidol, aripiprazole
- antidepressants such as amitriptyline, nortriptyline
- antibiotics to treat infection eg. dapsone, chloramphenicol, clarithromycin, doxycycline, ciprofloxacin, telithromycin
- antifungal medicine eg. fluconazole, itraconazole, ketoconazole, voriconazole
- antiviral medicine eg. saquinavir, ritonavir, indinavir, efavirenz, amprenavir, nelfinavir, atazanavir, lopinavir, nevirapine
- praziquantel, for worm infestations
- medicine to lower fat levels (cholesterol, triglycerides) in the blood eg. simvastatin, clofibrate
- cancer medicine eg. irinotecan, imatinib
- quinine, often used for night cramps
- riluzole, used in motor neurone disease (MND)
- theophylline, for asthma
- anti-sickness medicine eg. ondansetron
- atovaquone, for malaria or pneumonia

- antacids used for indigestion. Take Rifampicin 300mg Capsules at least 1 hour before taking antacids
- other medicines used for tuberculosis such as isoniazid or p-aminosalicylic acid (PAS). Rifampicin 300mg Capsules and PAS should be taken at least 8 hours apart.

Inform your health care provider that you are using or have previously used Rifampicin 300mg Capsules before you undergo surgery. This is because Rifampicin 300mg Capsules and some anaesthetics (e.g., halothane) should not be taken together.

### **Pregnancy and breast-feeding**

If you become pregnant, or are planning to become pregnant, you must contact your health care provider to discuss the potential benefits and risks of the tuberculosis therapy for you and your child.

Rifampicin is excreted into breast milk of breast-feeding mothers. No negative effects have been reported in breast-fed infants whose mothers were receiving these drugs. However, drug concentrations in breast milk are so low that you cannot rely upon breast-feeding for adequate tuberculosis prophylaxis or therapy for your child.

If you want to breast-feed your baby, you should ask your health care provider for advice on the risks and benefits.

### **Driving and using machines**

Rifampicin 300mg Capsules may cause visual disturbances or tingling or numbness in the hands and feet. They can affect the ability to drive and to use machines.

### **Excipients**

Rifampicin 300 mg Capsules contains the following agents which may cause allergic reactions:

0.7 mg carmoisine (azorubine), 0.1728 mg sodium methyl parahydroxybenzoate, 0.0192 mg sodium propyl parahydroxybenzoate, 0.28 mg sunset yellow (FD&C yellow #6) and 0.196 mg ponceau 4R (cochineal red A).

### **3. HOW TO TAKE RIFAMPICIN 300MG CAPSULES**

Rifampicin 300 mg Capsules should always be taken exactly as described by the health care provider. Check with your health care provider if you are not sure.

#### **Taking Rifampicin 300 mg Capsules with food and drink**

Rifampicin 300 mg Capsules should be taken on an empty stomach (at least one hour prior to or two hours after a meal).

You should not drink alcohol while taking Rifampicin 300 mg Capsules. This increases the risk of liver damage.

The dose of Rifampicin 300 mg Capsules is decided on the basis of body weight as follows:

#### *Adults:*

10mg/kg (8-12mg/kg) daily or 3 times weekly, maximum 600mg (2 capsules)

#### *Children (only for children who can swallow capsules):*

10-20mg/kg daily, maximum 600mg (2 capsules)

Your health care provider will decide on the duration of treatment that is suitable for you.

Rifampicin 300 mg Capsules should be swallowed with water or another drink.

#### **If you take more Rifampicin 300 mg Capsules than you should**

If you take too many capsules, you may develop nausea or vomiting (feeling or being sick), stomach pain, itching, headache and an increasing feeling of drowsiness. You may also get a reddish-orange discolouration of the skin, facial swelling and itching.

You should immediately contact a health care provider or the nearest hospital emergency department for further advice. Remember to take the pack and any remaining capsules with you.

#### **If you forget to take Rifampicin 300 mg Capsules**

If you miss or forget to take a dose, the missed dose should be taken as soon as possible, unless the next regular dose is scheduled dose within 6 hours.

Skip the missed dose if it is almost time for the next regular dose.

You should not take a double dose to make up for forgotten individual doses.

#### **If you stop taking Rifampicin 300 mg Capsules**

You should keep taking the medicine for as long as your health care provider has ordered, even if you are feeling better. If you stop the medicine too soon, the infection may not be completely cured. You should not stop treatment unless your health care provider says so.

If you have any further questions on the use of this product, ask your health care provider.

#### 4. POSSIBLE SIDE EFFECTS

Like all medicines, Rifampicin 300 mg Capsules can cause side effects, although not everybody gets them. When treating tuberculosis, it is not always possible to differentiate between unwanted effects caused by Rifampicin 300 mg Capsules, and those caused by any other medicines you may be taking at the same time. For this reason, it is important that you inform the health care provider of any change in your health.

**If any of the following happen, stop taking Rifampicin and tell your health care provider immediately:**

Allergic reactions such as swollen skin or swelling of the face, lips, tongue or throat which may cause difficulty breathing or swallowing

- Small purple spots or unusual bruising or bleeding of the skin, or a sudden, severe headache
- Bleeding from your nose, ear, gums, throat, skin or stomach. You may notice a feeling of tenderness and swelling in your stomach, purple spots on your skin and black or tar-like stools
- Severe diarrhoea possibly with blood in the stools
- Liver problems which may cause dark urine, pale stools, yellowing of the skin or whites of the eyes (jaundice)
- Kidney problems which may cause blood in the urine, a change in the amount of urine passed, and feeling drowsy or weak
- Severe skin reactions including blistering of the skin, mouth, eyes and genitals, and swollen blood vessels in the skin.

These side effects are serious. You may need medical attention.

**Tell your health care provider straight away** if you notice any of the following side effects:

- Flu-like symptoms with fever, chills, headache, dizziness and bone pain
- Shortness of breath and wheezing
- Mental problems causing a change in personality, hallucinations and odd behaviour
- Signs of shock such as clammy, cold skin, a racing heartbeat and shallow breathing
- Very rare effects include blood changes causing symptoms such as fever, feeling unusually tired, chest pain, sore throat, mouth ulcers or suffering from more infections than usual. Tell your health care provider straight away if you notice any of these effects.

**Other side effects are:**

- Itchy skin with or without a rash
- Flushing
- Loss of appetite
- Nausea or vomiting (feeling or being sick)
- Stomach pain
- Diarrhoea
- Low blood pressure
- Your tears, urine, sweat and saliva may turn a reddish colour. If you wear soft contact lenses, Rifampicin may permanently stain them.
- Muscle weakness, pain or wasting
- Swelling of the legs and ankles
- Irregular periods, more likely if on long-term treatment

**Reporting of side effects**

If you get any side effects, talk to your healthcare provider. This includes any possible side effects not listed in this leaflet.

## 5. HOW TO STORE RIFAMPICIN 300 MG CAPSULES

Keep out of the reach and sight of children.

Store at a temperature not exceeding 25°C, in a dry place, protected from light. Dispense in tight container.

*Blister pack:* Store capsules in blisters in the provided carton.

Do not use Rifampicin 300 mg Capsules after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Medicines should not be disposed of in wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## 6. CONTENTS OF THE PACK AND OTHER INFORMATION

### What Rifampicin 300 mg Capsules contains

The active ingredient of Rifampicin 300 mg Capsules is 300 mg of rifampicin.

The other ingredients in the capsule fill are: microcrystalline cellulose, povidone, maize starch, sodium lauryl sulphate, purified talc and magnesium stearate.

The ingredients in the capsule shell are: gelatin, sodium methylparahydroxybenzoate (E219); sodium propyl parahydroxybenzoate (E217); sodium lauryl sulphate; titanium dioxide (E171), sunset yellow/FD&C Yellow #6 (E110); carmoisine/azorubine (E122); and ponceau 4R/cochineal red A (E124).

### What Rifampicin 300 mg Capsules looks like and contents of the pack

Blister packs of 10 x 10 capsules

10 capsules packed in clear PVC-Alu blister cards. Such 10 blister cards are packed in a box (carton) along with the patient information leaflet.

Strip packs of 10 x 10 capsules

10 capsules packed in Alu-Alu strips. Such 10 strips are packed in a box (carton) along with the patient information leaflet.

Bottle pack of 100 capsules

100 capsules packed in a self-sealing LDPE bag, put in a plain triple laminated sachet (LDPE/PET-Alu); the triple laminated sachet is kept in a round, wide mouth, opaque, milky white HDPE container sealed with a tagger and closed with a screw thread cap (HDPE), along with the patient information leaflet.

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Detailed information on this medicine is available on the World Health Organization (WHO) web site:  
<https://extranet.who.int/prequal/>